**Purpose:**

The quality assurance plan (QA) at Bioreach Laboratories addresses the entire laboratory process: pre-analytical, analytical, and post-analytical phases. A quality assessment program is developed and implemented to assess and improve the reliability and efficiency of the laboratory, to ensure that the highest possible quality of service is provided, and to comply with regulatory requirements. QA refers to planned, step-by-step activities that let one know that testing is being carried out correctly, results are accurate, and mistakes are found and corrected to avoid adverse outcomes. QA is an ongoing set of activities that help to ensure that the test results provided are as accurate and reliable as possible for all persons being tested. QA procedures should be in place during the entire testing process, from the time a person asks to be tested to providing the test result.

**Goals:**

The goals of the QA program are to:

* Improve the overall quality and efficiency of the laboratory service.
* Evaluate the effectiveness of the laboratory’s policies and procedures
* Identify problems and make corrections to prevent recurrences
* Prevent recurring problems
* Assure accurate, reliable, and prompt performance of tests and reporting results

**Analytical Checklist – Reagent Integrity and Instrument Maintenance, Calibration/Calibration Verification, QC Review:** Analytical

Frequency – Monthly QA review.

Method of Review – Inspection of records

**Patient Test Management:** Pre & Post Analytical

Frequency – Monthly with Monthly QA/QC Assessment

Method of Review – Random Chart Audit, Inspection of records

**Personnel:**  Pre-Analytical

Frequency – Annual

Method of Review – CLIA designated Competency Assessments, Review of personnel files

**Procedure Manual:** Pre-Analytical & Analytical

Frequency – Annual or as needed.

Method of Review – Review of procedure manual and approval records

Laboratory Director approval of policies: Biannual approval by Lab Director or upon creation or revision of policies.

**Proficiency Testing:** PT surveys from all PT providers.

Frequency – On-going with annual assessment/check for completeness.

* Method of Review – Audit of the PT Binder for all PT events. Proficiency Testing Review Form will be used to track all steps of each PT event from start to finish, including review of the evaluation report by testing personnel and laboratory director and investigation of any failures. All required paperwork must be retained with the checklist and evaluation report. Retention time is two years.

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**Laboratory Information Systems (LIS)**

Frequency – Initial and after major updates or format changes as applicable

Method of Review – Comparison of actual results or calculations with same information in LIS to assure accuracy. Documentation of LIS accuracy checks to be kept with Monthly QC/QA assessment as needed.

**Quality Assurance Plan**

Frequency – Annual

Method of Review – Review the current plan to determine if the monitors, frequency, and method of review have been effective in identifying and correcting problems in a timely manner. Adjustments or modifications to the plan are made as determined necessary by the laboratory director and testing staff.

**IMPLEMENTATION**

* Quality Assessment Reviews are conducted at the frequency specified
* The Quality Assessment Forms associated with the monitor are completed
* If a problem is identified, corrective action is implemented, and a follow up review is conducted to assure that the corrective actions have resolved the problem.
* The QA Review forms are signed and dated by the reviewer and laboratory director and retained in the Quality Assessment folder for a minimum of two years (3 years for California).

**Annual Calendar of QA Reviews**

*All Quality Assessment Documentation must be retained for a minimum of two years.*

1. Review the monitor (s) assigned for each month. Document the review on the appropriate form and attach all supporting data and information.
2. **Annually**, complete the Analytical, Proficiency, Personnel, and Procedure Manual checklists. The Analytical Checklist includes Maintenance, Calibration/Calibration Verification, Quality Control, Temperatures, and Reagents. Review as applicable.

| **Jan** | **Feb** | **March** | **April** | **May** | **June** |
| --- | --- | --- | --- | --- | --- |
| QA/QC Annual Plan Review, Safety plan review, CLIA personnel review | Monthly QA/QC Check. | Monthly QA/QC Check | Monthly QA/QC Check | Monthly QA/QC Check | Monthly QA/QC Check, 6 month analyzer correlation |
| **July** | **Aug** | **Sep** | **Oct** | **Nov** | **Dec** |
| Monthly QA/QC Check | Monthly QA/QC Check | Monthly QA/QC Check | Monthly QA/QC Check | Monthly QA/QC Check | Monthly QA/QC Check, 6 month analyzer correlation |

**QUALITY IMPROVEMENT/ PERFORMANCE IMPROVEMENT MONITORS**

**“Quality improvement monitors”** are processes or events that reveal how well the laboratory is functioning. Monitoring Quality improvement monitors results in the identification of problems significant enough to require review, analysis, and implementation of appropriate corrective action. Quality improvement monitors should be simple and definitive. Once a problem has been identified, an analysis of what caused the problem must be performed. The cause must be identified so appropriate corrective action can be implemented to prevent a recurrence of the problem in the future.

Quality improvement monitors should be selected for each of the following categories: test or procedure management and performance, appropriate utilization of services, proficiency testing, user satisfaction, safety, quality control, observed or reported incidents, and competency of personnel. The chosen Quality improvement monitors should be reviewed periodically. The review should monitor for frequency and/or trends of identified problems. If a pattern exists additional analysis is required to further investigate the source of the problem. Additional corrective action may need to be implemented to eliminate the problem.

Areas to be reviewed for potential Quality Improvement monitors:

**Pre-analytical Phase**

a. Patient Preparation: Examples:

1. Non-fasting - lipid profile.

2. Written instructions

b. Specimen collection: Examples

1. Unlabeled collection cup

2. Hemolyzed specimens

c. Specimen labeling and accessioning

1. Mislabeled specimens

2. Tracking system for referred specimens

d. Specimen preservation/transport/storage

1. Transport times for samples collected off-site

e. Test requisitions

1. Completeness of requisition forms

f. Relevance of test requests

1. Request consistent with diagnosis

2. Age and gender appropriateness

g. Specimen rejection criteria and actions initiated

1. Specimen integrity acceptable

2. Proper patient preparation

i. Evaluation and verification of employee competence, knowledge, and skills

1. Competency assessment program covers all disciplines

2. Effective remedial training provided for unsatisfactory competencies

j. Safety

1. Employee training is up-to-date

2. Material Safety Data Sheets (MSDSs) are complete and up-to-date

k. Procedure updates and reviews

1. Annual review has been performed

2. All necessary revisions have been completed.

**Analytical Phase**

a. Instrument monitoring, including instrument validation and operation functions, inspections and preventative maintenance activities, and operational parameters.

1. Preventative maintenance is consistent with manufacturer’s recommendations

2. Function checks performed according to schedule

b. Calibration and calibration verification activities

1. Calibration and/or calibration verification performed according to manufacturer’s recommendation, and at least once every 6 months

2. Calibration when indicated based on quality control data

c. Quality control evaluations

1. Number and level of controls appropriate for complexity

2. Control ranges appropriate for each assay

d. Proficiency Test results

1. When available, PT performed on all analytes. If outside PT sources are not available, develop in-house procedure.

2. Appropriate corrective action taken for all failed PT analytes

e. Comparative analysis for multiple analyte methodologies/multiple locations

1. Comparisons performed for each method at all sites

2. Relevant criteria established for result comparison

f. Quality management of laboratory supplies, reagents, and materials

1. Inventory control efficient and follows manufacturer’s recommendations

2. Expired supplies, reagents, and materials discarded when expiration exceeded

**Post-analytical Phase**

a. Appropriateness and acceptability of test results

1. Results within reportable range for test

2. Reference ranges appropriate for patient population

b. Completeness of test reports

1. Patient name, lab name, test, result with units, and normal range included

2. Results reported for all tests ordered

c. Timely reporting of all test results

1. Results reported within established turnaround time

d. Accuracy and reliability of test reporting systems

1. Investigation of corrected reports

2. Reports sent to appropriate physician/department

e. Appropriate storage and retrieval of records of test results

1. Reports accessible and may be promptly retrieved

2. Records stored for required interval

f. Problems in communicating with physicians or other health care workers

1. Mechanism available for communication of problems

2. Effectiveness of corrective action for communication problems

g. Complaint investigation and evaluation and corrective actions initiated

1. Mechanism available for communication of complaints

2. Effectiveness of corrective action for complaints

h. Compliance with regulatory requirements

1. Accreditation requirement met

2. Safety requirement met

i. Incidence reports

1. Incident reporting system established

2. Follow-up to incidents evaluated for effectiveness

j. Review of QA reports with staff

1. QA findings are reported to staff periodically

2. Operating changes resulting from QA findings are reported to staff in a timely manner

**EMPLOYEE RESPONSIBILITIES**

Each laboratory employee shares in the responsibility of making sure that the patient receives the highest quality service available. Quality assessment monitors the performance of the laboratory services throughout all phases of the process. Because employees are one of the primary variable that can cause a change in the process, they must play close attention to policies and procedures.

Employees are responsible for monitoring and documenting the elements of the Quality Assessment Plan. It is important that each employee completely understand the quality assessment process and closely follow the requirement of the plan.

Laboratory management and administration are responsible for evaluating the monitored information, identifying causes when problems occur, initiating corrective actions, and following up to evaluate the effectiveness of actions taken when needed.

**SECTION II QUALITY ASSESSMENT PLAN**

Laboratory Bioreach Laboratories Clinical Laboratory

**RESPONSIBILITY FOR IMPLEMENTING AND ADMINISTRATION OF PLAN**

The Laboratory Director is directly responsible for ensuring the quality of services and reporting of data provided to referring physicians. Dr. Ammon Bayles, HCLD is responsible for ensuring that the Quality Assessment Plan is coordinated supervisory and testing personnel.

**Delegation of responsibilities:**

Safety Administration – Laboratory Manager

Review of Laboratory Results – Laboratory Manager/All staff

Corrective Action for Improvement of Care – Laboratory Manager

Monitor Corrective Action Effectiveness – Laboratory Manager

Equipment and Inventory – Laboratory Manager/All staff

**PROCEDURE**

1. Document problems or events on a daily basis*.*

2. Schedule reviews and conduct them according to the schedule.

a. Perform all monthly quality assessment activities listed on the review schedule. Use the *Quality Assessment Monthly Review* to record all findings.

b. Perform this audit on a random selection of patient files from Manually resulted log. (Laboratory testing should have been performed on these patients some time during the period under review.) Assess each record according to the policy and procedure for each critical indicator listed above. Ensure any manual reported results were appropriately transcribed.

d. Perform all annual quality assessment activities listed on the review schedule. Use the *Annual Quality Assessment* form to document completion of annual assessment.

e. Investigator and document proficiency test failures using the *Proficiency Test Corrective Action* form and the *Proficiency Test Failure Investigation Checklist*.

3. Evaluate the review to determine if any corrective action is needed.

a. If no problem is identified the review for this time-period is finished. Review this item during the next scheduled quality assessment review.

b. If a problem is identified, decide what corrective action is needed. Take the necessary corrective action and schedule a follow-up review to decide if the corrective action resolved the problem.

4. Document all reviews, corrective action and follow-up activities. Written documentation with specific facts is necessary to substantiate that the corrective actions did, in fact, resolve the issue.

1. Retain quality assessment records for a minimum of 2 years.

**MONTHLY AND ANNUAL REVIEWS**

| ELEMENT | CRITICAL INDICATOR | ACCEPTABLE LIMITS | METHOD |
| --- | --- | --- | --- |
| PROFICIENCY TESTING | Proficiency testing (PT) documentation reviewed regularly. Appropriate corrective action taken for all PT analytes | PT documentation is to be reviewed by lab Director or Laboratory Supervisor within 2 months of receipt of scorecard. | Review all PT documentation received within review period  Utilize Proficiency Test Corrective Action Form, and PT Failure Checklist to investigate failures |
| PROCEDURE REVIEWS | Procedures reviewed annually | Each procedure reviewed & signed by Lab Director within 24 months of previous review | Check for review signatures and date for each procedure |
| PERSONNEL | Competency assessment is comprehensive | Competency assessment performed for all areas that tech works | Review personnel files |
| Laboratory Safety | On-going and Annual review of safety issues and safety policy. | Documented on Personnel Safety Checklist and filed in Personnel Manual | Review of Safety Policy annually |

**QUALITY ASSESSMENT INDICATORS: POLICIES**

**1. Pre-analytical Monitors**

**Policy:** Pre-analytical monitors will be designed to measure the quality of laboratory activities that occur prior to actual testing. These monitors will include reviews of patient preparation errors, specimen collection problems, inadequate or improper specimen labeling, and inappropriate specimen preparation or transportation. These monitors will include, but may not be limited to:

a. Patient Preparation

Document all incidents where a patient was not adequately or properly prepared, according to the specifications identified in the patient preparation section of the procedure manual

b. Specimen Collection

Document each incident involving specimen collection. Record any special circumstances that might have contributed to the problem. Laboratory management will evaluate the occurrences on a monthly basis to identify problems or patterns indicated by the report. If a pattern or cause for further analysis is determined by laboratory management, additional analysis will be conducted.

c. Specimen Labeling and Accessioning

All *specimens* received into the laboratory must have the following information on the specimen label:

* Patient first and last name
* Specific identification number of other unique identifier number

All *requisitions* received into the laboratory must have the following information on the requisition:

* Patient first and last name, sex and age or date of birth
* Date and time of collection and source of specimen
* Initials of staff receiving specimen and verifying patient I.D.

Document all instances of inadequate requisition and/or specimen information. Include the patient’s information, initials of the person receiving the specimen, date and time of collection and any other pertinent information.

d. Specimen Transport, Storage, Preservation

Each specimen improperly stored, preserved, or transported to the laboratory according to the specifications defined in the procedure manual must be documented. Include the date and time of receipt, the patient’s name, the condition of the specimen, the individual reporting the event, the individual responsible, and the disposition of the specimen. This should also be noted in the Comments section of the report.

e. Test Request Information

If test request information is incomplete or not in compliance with the procedure, the incident should be documented. Include the patient information, test(s) requested, solution to correct the problem, and the date and time of the order.

f. Specimen Rejections

Each specimen rejection due to failure to meet specimen integrity standards defined in the specimen collection and/or test procedure manual must be docuemented. Record reason for rejection and actions taken. This should also be noted in the Comments Section of the patient report.

g. Personnel Assessment

Personnel assessment monitors will be used to assess and evaluate the capabilities and skills for those performing the individual testing within the laboratory. These monitors will include the employee’s performance appraisal, competency assessment, training records, and certification records. Competency assessment may utilize proficiency testing, direct observation, or written test. Training records should include required training and continuing education. Problems noted during the assessment of personnel, such as an unsatisfactory performance appraisal or competency assessment, or failure to remain current in training and/or certification requirements will be documented and a plan of correction implemented.

j. Safety Monitors

Safety monitors will be developed to review the environment in which laboratory procedures are performed, the potential and known hazards to patients and staff, and the readiness of staff to recognize and respond to hazards. These monitors will be developed to allow the laboratory to meet the standards of accreditation bodies, professional organizations, and regulatory agencies as well as to detect, evaluate and track hazards to patients and staff.

1. SDS Documents and SDS Education

Employees will be educated in the proper use and understanding of Safety Data Sheets (SDSs). Safety meetings will address handling of all hazardous materials in the laboratory. Annual review of the hazardous products used in the laboratory and the associated MSDS’s will be conducted. Failure of an employee to comply with the safety requirements in the MSDS will be documented and reported to laboratory management.

2. Storage of Chemical Materials

All chemicals will be properly labeled and stored within the laboratory. Proper storage includes all necessary labeling, storage location, storage ventilation, and other specified storage requirements of the product.

3. Employee Exposure to Hazardous Materials

Laboratory personnel will comply with all laboratory and OSHA policies and procedures relating to the handling and disposal of potentially hazardous materials. Compliance with the Laboratory Safety Policy/Plan is mandatory. Any employee identified that is not in compliance must be reported to the laboratory management.

4. Staff Response During Fire and Disaster Drills

A record of employee response to fire and safety drills is to be maintained by the BIOREACH LABORATORIES. Evaluation of response time and availability of staff to perform tasks will be evaluated. Fire drills will be performed Annually.

k. Periodic Evaluation of Policies and Procedures

Policies and procedures will be periodically reviewed at least annually and inaccurate, ineffective or inappropriate policies and procedures will be revised based on the outcome of the evaluation.

**2. Analytical Monitors**

**Policy:** Prior to the reporting patient test results, the laboratory is required to check the manufacturer’s performance specifications provided in the package insert for accuracy, precision, reportable range, and reference ranges, for each new unmodified test. Analytical monitors will be designed to measure the various processes and aspects of laboratory operations that occur during the actual testing phase. These monitors will include reviews of instrument functions, reagents, testing process, and test results. These monitors will be conducted in the same way that patient samples are handled and are rotated through all testing personnel. These monitors will include, but may not be limited to:

a. Instrument Monitors

1. Instrument Validation/Operation Functions

Each incident where instrument start-up data is unacceptable must be recorded.

2. Inspections and Preventative Maintenance of Laboratory Equipment

When proper preventative maintenance or inspections have not been performed as specified in the procedure, a performance improvement monitor will be created. This record must be immediately presented to laboratory management for evaluation and corrective action.

3. Monitoring of Operational Parameters

All laboratory systems that have defined operational parameters (temperature, humidity, etc.) must be monitored and be maintained within the system’s specified parameters before testing can be performed. This includes both internal temperature and ambient temperature, humidity, electrical requirements, electronic requirements, utility requirements, etc. If any of the specified manufacturer’s parameters are not met, the laboratory Supervisor must be immediately notified and testing must not be performed.

b. Calibration or Calibration Verification Results

Calibration must be performed at least every six months as outlined in the manufacturer’s instructions using at a minimum three levels that are within the reportable range of the test. Each incident of instrument calibration or calibration verification failure must be recorded. Adhere to the quality control protocols, policies, and procedures when evaluating calibration procedures. The form must indicate the individual performing the calibration, the problem, actions taken, and solution to correct the problem.

c. Quality Control Monitors

1. Quality Control Results

For each incident where the quality control results are not within defined limits, remedial actions must be documented and corrective actions identified according to the requirements defined in the quality control manual. Problems that cannot be resolved must be immediately reported to laboratory management and recorded. This should indicate the individual performing the quality control, the problem, actions taken, and solution to correct the problem.

2. Identifying, Reporting, and Reconciling Trends, Drifts and Bias

Evaluate daily quality control data from all testing events for accuracy, precision, statistical relevance, trending, drifting, and bias as defined in the laboratory quality control manual and technical procedures. Remedial actions are required when events occur that are outside of acceptable quality control standards.

d. Proficiency Testing (PT)

Proficiency testing responsibilities will be rotated through the testing personnel. All proficiency testing will be conducted as if it were an unknown patient sample. All external PT samples will be used within the routine workload and analyzed by personnel who routinely test patient samples using the same primary methodology as for patient samples. All PT results will be reviewed by the Laboratory Supervisor and the Lab Director and documented. Every proficiency test failure will be investigated following the Proficiency Test Failure Investigation Checklist and followed up by the laboratory director. Results of the investigation will be recorded on the *Proficiency Test Corrective Action* form. Attach to report and file in QA Records, PT section. If any one individual is responsible for 2 or more failures within a 12 month period, further analysis will be conducted and the individual may be subjected to blind testing, if determined appropriate by the Laboratory Supervisor. Additional in-service training will be provided to those individuals who do not perform within the specified parameters.

e. Quality Management

Quality Improvement monitors will be developed to review the quality of equipment and supplies used in the course of providing laboratory services. Quality monitors will be utilized to meet the standards of accrediting bodies, professional organizations, and regulating agencies; to detect and evaluate problems that may affect the reliability and accuracy of laboratory services; and to track progress in resolving problems affecting the reliability and accuracy of services.

**3. Post-analytical Monitors**

**Policy:** Post-analytical monitors are designed too measure the various processes and aspects of laboratory operations that occur following the actual testing process. These monitors will include review of test results, appropriateness of test results, completeness of test reports, adequacy of report storage and retrieval, and timely reporting of test results. Also included in the post-analytical monitors are those areas which cross over all analytical phases, such as complaints, communications, and regulatory compliance. These monitors will include, but may not be limited to:

a. Appropriateness and Acceptability of Test Results

Each test result that appears inconsistent with the patient’s age, sex, diagnosis, symptoms, or condition must be reported to the Laboratory Supervisor. Record the suspected problem and the individual identifying the concern. The appropriateness of the various criteria used by the laboratory will be evaluated, docuemted and shared with staff.

b. Completeness of Test Reports

Each instance of an incomplete test report must be documented. A complete test report includes all pertinent patient demographic information, all requested test results, all relevant expected ranges, and any notes or comments regarding the testing process or condition of the specimen. Record the observations and the individual identifying the problem.

c. Timely Reporting of Results

This reporting process must be adequately documented including the name of the individual responsible for reporting the findings and the individual that was notified.

d. Accuracy in Test Reporting

Each incident involving erroneously reported patient test results will be documented. A corrected report must be issued and a copy attached to the original report in the laboratory file. The original report and the corrected copy will also be reviewed by the laboratory management staff.

e. Report corrections

* 1. Typo and/or transcription errors - immediate correction
  2. Procedural error - immediate or deferred correction (which ever provides greatest potential for accuracy and precision and in the most immediate time-frame)
  3. Inaccurate or incorrect result - immediate or deferred correction (which ever provides greatest potential for accuracy and precision and in the most immediate time-frame)

f. Report Storage and Retrieval

The accuracy and reliability of the storage and retrieval system for laboratory test reports and records will be monitored. This review will be a random selection of 5 patient names taken from the last month of patient testing records.

g. Communications

Each instance of miscommunication, lack of proper communication, expressed concerns, problems or incidents must be documented. Communication problems include errors in the distribution of report results, failure of individuals to receive messages, communications breakdown between departments within the facility, inappropriate comments or statements, and all other types of communication errors or problems. All identified problems in communications will require corrective actions and these actions must be documented in detail.

h. Complaint Investigations

When a verbal or written complaint is lodged against the laboratory or an individual employed by the laboratory, a performance/quality improvement monitor. The complaint may be from any source including patients, providers, laboratory staff or other departments. Laboratory management will evaluate the complaint and take necessary corrective action.

i. Compliance with Regulatory Requirements

Incidents of non-compliance with regulatory requirements including, but not limited to, OSHA, CLIA, or fraud and abuse legislation should be documented. Laboratory management will take appropriate steps to correct these non-compliance incidents. Laboratory management will be responsible for maintaining overall compliance with regulatory requirements.

j. Staff Assessment of QA Findings and Outcomes

All findings, remedial actions, corrective actions, and follow up reviews will be reported to all laboratory staff members at monthly departmental QA meetings. All required changes and/or modifications will be conveyed to staff.

n. Records and Reviews

All documentation of quality assessment will be monitored by laboratory management. All QA records will be maintained in an organized system for a minimum of 2 years. Maintenance of QA documentation originates with the individual performing the procedures or functions relating to QA. Quality assessment reviews will be conducted according to schedule or as needed. Specific conclusions will be drawn from the findings of the review of the above indicators, as necessary, along with additional evaluation and research as indicated. A follow-up review will be performed to determine if the problems have been corrected.

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**QUALITY ASSESSMENT INCIDENT REPORT FORM**

Date of Incident:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Incident Report Prepared by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

DESCRIPTION OF INCIDENT:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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INVESTIGATION AND FINDINGS:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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CORRECTIVE ACTION TAKEN:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Lab Supervisors Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

FOLLOW-UP:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Lab Director Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**CUSTOMER COMMENT FORM**

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Location:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Customer Name (Optional):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Customer Type: Patient:\_\_\_\_\_ Provider:\_\_\_\_\_\_\_ Lab Staff:\_\_\_\_\_\_\_

Other Department:\_\_\_\_\_\_\_\_\_ Dept. Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Comment Description:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigation and Findings:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Corrective Action Taken:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Follow-up Review Required? Yes\_\_\_\_ No\_\_\_\_ If yes, date scheduled:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewed by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Follow-up findings:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Follow-up Reviewed by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROFICIENCY TEST CORRECTIVE ACTION FORM, PAGE 1**

Shipment #:\_\_\_\_\_\_\_\_\_\_\_ Specimen #:\_\_\_\_\_\_\_\_\_\_ Analyte:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Date:\_\_\_\_\_\_\_\_\_\_\_\_ Report Date:\_\_\_\_\_\_\_\_\_\_\_\_

Reported Result Expected Result Expected Range

\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Does this failure represent unsatisfactory performance for this analyte, specialty, or

subspecialty in two or two out of three testing events? YES\_\_\_\_\_\_ NO\_\_\_\_\_\_

INVESTIGATION:

Indicate which areas were investigated [See PT Failure Investigation Checklist for details]:

1. Specimen Handling: Yes\_\_\_\_\_ No\_\_\_\_\_ N/A\_\_\_\_\_

2. Clerical Errors: Yes\_\_\_\_\_ No\_\_\_\_\_ N/A\_\_\_\_\_

3. Quality Control: Yes\_\_\_\_\_ No\_\_\_\_\_ N/A\_\_\_\_\_

4. Calibration: Yes\_\_\_\_\_ No\_\_\_\_\_ N/A\_\_\_\_\_

5. Instrument: Yes\_\_\_\_\_ No\_\_\_\_\_ N/A\_\_\_\_\_

6. Reagents: Yes\_\_\_\_\_ No\_\_\_\_\_ N/A\_\_\_\_\_

7. Testing Personnel: Yes\_\_\_\_\_ No\_\_\_\_\_ N/A\_\_\_\_\_

8. Procedure: Yes\_\_\_\_\_ No\_\_\_\_\_ N/A\_\_\_\_\_

9. Interpretation Errors: Yes\_\_\_\_\_ No\_\_\_\_\_ N/A\_\_\_\_\_

1. Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

FINDINGS:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**PT CORRECTIVE ACTION FORM, PAGE 2**

CORRECTIVE ACTION: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**COULD THIS ERROR AFFECT PATIENT RESULTS? Yes\_\_\_\_\_ NO\_\_\_\_\_**

If YES, state course of action:

Investigated by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewed by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROFICIENCY TESTING FAILURE INVESTIGATION CHECKLIST**

**Page 1**

1. Specimen Handling:

\_\_\_\_a. Were PT specimens checked for acceptability when received? (Review notes made at time PT test was performed). (Y, N or N/A)

\_\_\_\_b. Were the specimens handled properly? (Review instructions for specimen preparation) (Y, N or N/A)

1. Clerical Errors:

\_\_\_\_a. Verify correct value was transcribed from instrument printout form, or that the correct response was entered from the list of results.

\_\_\_\_b. Verify that decimal point and units of measure were entered correctly on report form.

\_\_\_\_c. Verify that the correct code from the instrument or reagent list was entered on the report form.

\_\_\_\_d. Verify that the correct testing method information was provided.

\_\_\_\_e. Check summary report to verify value on report form was entered correctly by PT service.

1. Quality Control:

\_\_\_\_a. Were controls in range on date of PT? (Y, N or N/A)

\_\_\_\_b. Any evidence of trending, shifting in periods just before and just after PT? (Y, N or N/A)

1. Calibration:

\_\_\_\_a. What was date of last calibration? \_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_b. How often is calibration to be performed? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_c. When was last calibration verification performed? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_d. Were any calibration problems noted? (Y, N or N/A)

1. Instrument:

\_\_\_\_a. Are instrument parameters entered correctly? (Y, N or N/A)

\_\_\_\_b. Was daily maintenance performed on date of proficiency testing? (Y, N or N/A)

\_\_\_\_c. Was special maintenance performed just prior to proficiency testing? (Y, N or N/A)

\_\_\_\_d. Were instrument problems noted when proficiency testing was performed(Y, N or N/A)

**PROFICIENCY TESTING FAILURE INVESTIGATION CHECKLIST**

**Page 2**

1. Reagents:

\_\_\_\_a. Check reagent/instrument log for notation of recent problems.

\_\_\_\_b. Check reconstitution instructions in the insert versus procedure—and changes? (Y, N or N/A)

\_\_\_\_c. Verify that open stability of reagent was not extended by reviewing procedure with testing personnel.

1. Testing Personnel:

\_\_\_\_a. Check date of last competency assessment for testing personnel.

\_\_\_\_b. Review assay procedure and proficiency test sample preparation instructions with testing personnel to ensure that instructions were followed.

\_\_\_\_c. Review with testing personnel how samples were loaded to rule out misidentification or transposition of samples.

1. Procedure:

\_\_\_\_a. Review procedure versus manufacturer’s most current recommendations for any changes.

\_\_\_\_b. Call instrument or reagent manufacturer for input if cause is not readily identified.

1. Interpretation Errors:

\_\_\_\_a. Was PT challenge beyond the scope and extent of the testing routinely performed in the lab? (Y, N or N/A)

\_\_\_\_b. Has summary report been reviewed for an explanation of key features of the element presented in the transparency? (Y, N or N/A)

\_\_\_\_c. Have textbooks references been consulted for additional information? Y, N or N/A)

\_\_\_\_d. (Microbiology) Compare the test characteristics found in the laboratory with the characteristics of the correct identification. Review your results and procedures for the key test to distinguish the correct identification from the incorrect identification.

NOTES:

**Bioreach Laboratory Monthly QA Review**

Month Reviewed\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date Performed:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

| ELEMENTS TO BE REVIEWED | FINDINGS ACCEPTABLE | INIITIALS |
| --- | --- | --- |
| **PRE-ANALYTICAL** |  |  |
| Personnel reviews up-to-date (Competency, Training) |  |  |
| Spot checks for Infection Control/Safety |  |  |
| Procedures updates approved by the lab director |  |  |
| Temp logs checks for completeness and accuracy |  |  |
| **ANALYTICAL** |  |  |
| Proficiency testing activities up-to-date w/ signed attestations. Ensure Scorecards are signed by LD |  |  |
| QC records reviewed/ backed up, including spot checks |  |  |
| Instrument maintenance records reviewed |  |  |
| Six Month correlation for paired analyzers |  |  |
|  |  |  |
| **POST-ANALYTICAL** |  |  |
| Results review/Manual entry review/Corrected report check |  |  |
| Errors/Problems/Complaints are corrected, documented and followed-up on |  |  |
| All quality assessment reviews are shared with the lab staff |  |  |

**Spot Check Documentation:** Hand Hygiene: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**IDENTIFIED ISSUES/CONCERNS:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**CORRECTIVE ACTIONS:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Attach additional documentation as needed).

Follow-up review scheduled for: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

This Quality Assessment document has been reviewed and approved:

Lab director, or designee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Bioreach Laboratories Annual Quality Assessment**

1. Monthly quality assessment report completed? Yes\_\_\_\_ No\_\_\_\_

Follow-up reviews completed, if applicable? Yes\_\_\_\_ No\_\_\_\_

1. Annual personnel assessments completed? Yes\_\_\_\_ No\_\_\_\_
2. Chemical inventory and MSDS audit completed? Yes\_\_\_\_ No\_\_\_\_
3. Policies and procedures reviewed? Yes\_\_\_\_ No\_\_\_\_
4. Proficiency testing events reviewed and all failures investigated? Yes\_\_\_\_ No\_\_\_\_
5. Comparison of test results reviewed? Yes\_\_\_\_ No\_\_\_\_
6. Required safety in-services conducted and attended? Yes\_\_\_\_ No\_\_\_\_
7. LIS Calculation/Reference Range audit completed? Yes\_\_\_\_ No\_\_\_\_

COMMENTS:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Follow-up Review Required? Yes\_\_\_\_ No\_\_\_\_ If yes, date scheduled:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewed by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Follow-up findings:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Follow-up Reviewed by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PERSONNEL SAFETY CHECKLIST**

**Acknowledgement of Receipt of Training**

OSHA 29 CFR Part 1910.1030 – Occupational Exposure to Bloodborne Pathogens

Date of Training\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Facilitator\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Purpose:\_\_\_\_\_ Initial Training \_\_\_\_\_ Orientation \_\_\_\_\_ Annual \_\_\_\_\_ Other/Retraining

**Summary of Training (Including but not limited to:)**

|  | 1. | Copy of OSHA Standard 29 CFR Part 1910.130 |
| --- | --- | --- |
|  | 2. | Explanation of the epidemiology and symptoms of bloodborne diseases |
|  | 3. | Modes of transmission of bloodborne disease |
|  | 4. | Review of Exposure Control Plan |
|  | 5. | Methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials |
|  | 6. | Use and limitations of methods that will prevent exposure |
|  | 7. | Types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment |
|  | 8. | Selection of personal protective equipment |
|  | 9. | Benefits of being vaccinated for Hepatitis B and that the vaccine will be offered free of charge |
|  | 10. | Actions to take and person to contact in an emergency involving blood or other potentially infectious materials |
|  | 11. | Procedures to follow if an exposure incident occurs |
|  | 12. | Post exposure evaluation and follow-up |
|  | 13. | Explanation of the signs and labels required |
|  | 14. | Questions and answer session |
|  | 15. | Medtraining.org safety training assessments completed. |
|  | 16. | Other: |
|  | 17. | Other: |

I have received training in the topics listed above. I was provided an opportunity to ask questions and receive answers and know that I may contact the facilitator listed above if I have additional questions.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Employee Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Lab Supervisor Signature Date